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(54) **METHODS AND COMPOSITIONS FOR DIAGNOSIS AND PROGNOSIS OF RENAL INJURY AND RENAL FAILURE**

(57) The present invention relates to methods and compositions for monitoring, diagnosis, prognosis, and determination of treatment regimens in subjects suffering from or suspected of having a renal injury. In particular, the invention relates to using a measured urine concentration of one or more of TIMP2 and IGFBP7 in combination with one or more of a measured serum creatinine

and a measured urine output, which results are correlated to the renal status of the subject, and can be used for diagnosis, prognosis, risk stratification, staging, monitoring, categorizing and determination of further diagnosis and treatment regimens in subjects suffering or at risk of suffering from an injury to renal function, reduced renal function, and/or acute renal failure.

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EUROPEAN SEARCH REPORT

Application Number
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DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
A	CARON ET AL: "Ischemia injury alters endothelial cell properties of kidney cortex: Stimulation of MMP-9", EXPERIMENTAL CELL RESEARCH, ACADEMIC PRESS, US, vol. 310, no. 1, 15 October 2005 (2005-10-15), pages 105-116, XP005093311, ISSN: 0014-4827, DOI: 10.1016/J.YEXCR.2005.07.004 * the whole document *	1-15	INV. G01N33/566 C12M1/34 C40B30/04 C40B60/12 G01N33/573 G01N33/68
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The present search report has been drawn up for all claims			
Place of search Munich		Date of completion of the search 25 August 2020	Examiner Moreno de Vega, C
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

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DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
Y	US 2012/283128 A1 (ANDERBERG JOSEPH [US] ET AL) 8 November 2012 (2012-11-08) * paragraph [0094] - paragraph [0097]; tables 1-7 *	1-15	
Y	WO 2011/035323 A1 (ASTUTE MEDICAL INC [US]; ANDERBERG JOSEPH [US]; GRAY JEFF [US]; MCPHER) 24 March 2011 (2011-03-24) * paragraph [0048]; claims 1-53 * * paragraph [0144] *	1-15	
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Place of search		Date of completion of the search	Examiner
Munich		25 August 2020	Moreno de Vega, C
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

1 EPO FORM 1503 03.82 (P04C01)



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CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing claims for which payment was due.

☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for those claims for which no payment was due and for those claims for which claims fees have been paid, namely claim(s):

☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for those claims for which no payment was due.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.

☐ As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.

☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:

☒ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:

1-15(partially)

☐ The present supplementary European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims (Rule 164 (1) EPC).



LACK OF UNITY OF INVENTION
SHEET B

Application Number

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The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. claims: 1-15(partially)

Method for evaluating renal status in a subject, comprising determining a measured value for at least TIMP2 concentration and a measured value for at least serum creatinine concentration, and combining the measured values obtained.

2. claims: 1-15(partially)

Method for evaluating renal status in a subject, comprising determining a measured value for at least urine IGFBP7 concentration and a measured value for at least serum creatinine concentration, and combining the measured values obtained.

3. claims: 1-15(partially)

Method for evaluating renal status in a subject, comprising determining a measured value for at least TIMP2 concentration and a measured value for at least urine output, and combining the measured values obtained.

4. claims: 1-15(partially)

Method for evaluating renal status in a subject, comprising determining a measured value for at least IGFBP7 concentration and a measured value for at least urine output, and combining the measured values obtained.

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

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5 This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

25-08-2020

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